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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,287	07/15/2003	Patrick J. Sweeney	029815-0102	7722

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/620,287	Applicant(s) SWEENEY, PATRICK J.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/26/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 3/26/2008 in which claims 1-3, and 13 were amended. Currently claims 1-17 are pending for examination in this application.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 03/26/2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant cites the specification ([0037]) in which the insert is mentioned as aligning or not aligning with the fenestrations, not completely blocking the fenestrations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Spievack et al. (USPN5,871,484). Spievack et al. discloses an apparatus and method for administering biologically active substance to a bone.

Regarding claims 1 and 13, Spievack et al. discloses a device (90) for delivering a substance to a bone (col 1, ln 30-60), the device comprising: (a) a bone screw (92) comprising two ends connected by a shaft, wherein the shaft is cannulated (95) along at least a portion of its length; (b) one or more bone-screw fenestrations (94) disposed along the cannulated portion of the bone-screw shaft; and (c) an insert (30) disposed inside the cannulated bone-screw shaft wherein the insert is capable of completely blocking all of the bone screw fenestrations (via seals 35) from fluid flow, wherein the insert comprises two ends connected by a shaft and is cannulated along at least a portion of its length, and further wherein the insert comprises a section (30) between the two ends of the insert that is permeable to the substance to be delivered to the bone (Figures 1-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3763

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C 103(a) as being unpatentable over Wilcox et al. (US5,681,289) in view of Sasso et al. (US2004/0225292) (or Chappius (US2001/0021852)). Wilcox et al. discloses a chemical dispensing system.

Regarding claims 1-17, Wilcox et al. discloses a device (87,105) for delivering a substance to a bone (85), the device comprising: a bone rod (87,105) used for fixation comprising two ends connected by a shaft, wherein the shaft is cannulated (88) along a portion of its length; one or more fenestrations (90,109) disposed along the cannulated portion of the bone rod shaft; an insert (100,110) disposed inside the cannulated bone screw, wherein the insert comprises two end connected by a shaft and is cannulated (103) along at least a portion of its length, wherein the insert is capable of being moved to align or not align with the fenestrations for blocking the fenestrations and preventing backwards fluid flow through the device (via the plugs 101 and bladder 101a); and one or more fenestrations (105,112) disposed along the cannulated portion comprising a permeable section of the insert to provide a delivery pathway for a substance between

Art Unit: 3763

at least one end of the bone screw (89, 96) (Figures 8-10) (Figures 11-13). Wilcox et al. also discloses multiple embodiments in which reservoirs are present: an external tube (91), pump (127) or subcutaneous pump (62) in which the therapeutic fluid can be introduced into the system (Figures 6, 9 and 14).

Sasso et al. (or Chappius) meets the claim limitations as described above except for the bone screw and specific materials.

However, Sasso et al. teaches a bone anchor and methods of using the same and Chappius teaches a fenestrated surgical screw and method.

Regarding claims 1-17, Sasso et al. teaches a device (10) for delivering a substance to a bone comprising a bone screw (12) comprising two ends (12a, 22) connected by a shaft wherein the shaft (30) is cannulated along a portion of its length, one or more bone-screw fenestrations disposed along its length to provide a delivery pathway for substance through the bone-screw (Figures 1-12). Additionally, the screw is self tapping ([0023]) and the screw is composed of various alloys ([0033]), and the screw is capable of being used for fixation (Figure 12). Sasso et al. further discloses a substance reservoir (5) attached to the end of the bone screw (Figure 5).

Regarding claims 1-17, Chappius teaches a device (10) for delivering a substance to a bone comprising a bone screw (Figure 1) comprising two ends (14, 16) connected by a shaft wherein the shaft (near 22) is cannulated (22) along a portion of its length, one or more bone-screw fenestrations (24) disposed along its length to provide a delivery pathway for substance through the bone-screw (Figures 1-10). Additionally, the screw is self tapping (Figure 2) and the screw is composed of various alloys ([0027]),

and the screw is capable of being used for fixation (Figure 12). Chappius further discloses a substance reservoir (Figures 8-9) attached to the end of the bone screw.

At the time of the invention, it would have been obvious to add the spiral grooves of Sasso et al. (24) or Chappius (22) in order better fix the rod into the bone and allow for better bone healing. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Sasso et al. ([0001-0014]) or Chappius ([0001-0013]).

Response to Arguments

Applicant's arguments filed 3/26/2008 have been fully considered but they are not persuasive. Applicant's representative asserts that the prior art references do not disclose the claim limitation of the insert being movable between a first and second position where the positions block the fenestrations or allow for fluid delivery.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the Wilcox et al. (USPN5,681,289) reference is capable of meeting the claim limitation. Wilcox et al. is capable of being used in an aligned and no aligned state to allow for fluid delivery or block fluid flow because the bladder (101) can be inflated to press the insert against the wall sealing the cannulated nail cavity.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of the fenestrated insert or further clarification of how the insert functions (Figures 5A, 6) as described in Applicant's specification ([0037]) with regards to alignment of fenestrations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3763

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/21/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763